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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,252	01/07/2000	Avi J. Ashkenazi	P0978P3C1	2825

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07/15/2003

GENENTECH INC
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EXAMINER

BUNNER, BRIDGET E

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/479,252

Applicant(s)

ASHKENAZI ET AL.

Examiner

Bridget E. Bunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 18, 19, 22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowable.
- 6) ☒ Claim(s) 1, 18, 19, 22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 13 May 2000 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 13 May 2003 (Paper No. 12) has been entered in full. Claims 1 and 3 are amended and claims 4-6 are cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 18-19, 22, and 25 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to the specification at pg 2-3 of the previous Office Action (Paper No. 9, 13 November 2002) is *withdrawn* in view of the amended first sentence of the specification (Paper No. 12, 13 May 2003).
2. The rejection of claim 3 under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e) as set forth at pg 3-4 of the previous Office Action (Paper No. 9, 13 November 2002) is *withdrawn* in view of Applicant's persuasive arguments (Paper No. 12, 13 May 2003).

Information Disclosure Statement

3. The information disclosure statement filed 18 April 2000 (Paper No. 5) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. It is noted to Applicant that the cited references were not found to be included with prior application 09/060,533. It is also noted that a previous Examiner initialed the same PTO-1449 form in the 09/060,533 application. However, in order

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for the references to be considered in the instant case, the Examiner suggests resubmitting them via mail or hand-carry deliver.

Sequence Compliance

4. The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (Paper No. 12, 13 May 2003) has been considered and is found *persuasive in part*. It is noted that the claim amendments of 13 May 2003 now recite sequence identifiers. However, the sequences disclosed in Figure 1B are still not accompanied by the required reference to the relevant sequence identifiers. Applicant indicated in the Response of 13 May 2003 (Paper No. 12) that a supplemental Sequence Listing for the application was to be filed in compliance with the requirements under 37 CFR 1.821-1.825. No supplemental sequence listing has been received by the PTO at this time. Therefore, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Appropriate correction is required.

Drawings

5. The corrected or substitute drawings were received on 13 May 2003 (Paper No. 13). The drawings will be forwarded to the draftsman once allowable subject matter has been identified.

Claim Rejections - 35 USC § 102(a) and 35 USC § 102(e)

6. Claims 1, 18-19, 22, and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Wiley et al. (Immunity 3(6): 673-682, Dec. 1995). Claims 1, 18-19, 22, and 25 are also rejected under 35 U.S.C. 102(e) as being anticipated by Wiley et al. (U.S. patent 5,763,223). The basis for these rejections is set forth for claims 1, 3-6, 18-19, 22, and 25 at pg 3-4 of the previous Office Action (Paper No. 9, 13 November 2002).

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It is noted that the claims are directed to an isolated soluble ligand polypeptide comprising amino acid residues 91-281 of Figure 1A (SEQ ID NO: 1) and an isolated soluble ligand polypeptide consisting of amino acid residues 91-281 of Figure 1A (SEQ ID NO: 1). The claims also recite a composition comprising the Apo-2 ligand polypeptide and a carrier. The claims recite that the composition useful for stimulating mammalian cell apoptosis comprises the Apo-2 ligand polypeptide. The claims also recite that the Apo-2 ligand polypeptide comprises an N-terminal methionine.

Applicant's arguments (Paper No. 12, 13 May 2003), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that neither Wiley et al. reference teaches or suggests an Apo-2 ligand polypeptide having amino acid residues 91-281. Applicant contends that the Examiner has referred to various portions of the Wiley et al. references regarding the TRAIL protein. Applicant argues that it is clear there is no description in these references to a 91-281 form of the protein.

Applicant's arguments have been fully considered but are not found to be persuasive. It is noted to Applicant that, for example in claim 1, which recites "an isolated soluble ligand polypeptide comprising amino acid residues 91-281 of Figure 1A (SEQ ID NO: 1)", the term "comprising" is interpreted by the Examiner as open terminology. Therefore, the term "comprising" still allows the inclusion of other, larger nucleotide sequences that encode the protein. (See MPEP § 2111.03; *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997).) Therefore, Wiley et al. teach an isolated soluble protein, designated TNF-related apoptosis-inducing ligand (TRAIL) that is 100% identical to the

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Apo-2 ligand polypeptide of the instant application comprising amino acids 91-281 of SEQ ID NO: 1 (see sequence alignments attached to previous Office Action as Appendices A and B; see pg 675, col 1 and amino acids 91-281 of Wiley et al.; see col 28-29, example 7 and amino acids 91-281 of U.S. patent 5,763,223; see also Figure 1A and amino acids 91-281 of SEQ ID NO: 1 of the instant application). The TRAIL protein identified by Wiley et al. that corresponds to amino acids 91-281 of SEQ ID NO: 1 of the instant application comprises an N-terminal methionine residue (see sequence alignments attached to previous Office Action as Appendices A and B; see amino acids 91-281 of Wiley et al. and U.S. patent 5,763,223). Additionally, Wiley et al. disclose that TRAIL induces apoptosis in many different types of cells, including mammalian cancer cells (pg 675-676; pg 678, col 1-2; Table 1 of Wiley et al.; col 26-27, example 5; col 29-30, example 8 ; Table 1 of U.S. patent 5,763,223). Wiley et al. treat the cells with conditioned supernatant from cells transfected with the soluble TRAIL construct, which is a composition (pg 680, ¶ 2 of Wiley et al.; col 28-29, example 7 of U.S. patent 5,763,223).

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Conclusion

Claim 3 is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
July 9, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER